(12) UK Patent Application (19) GB (11) 2 364 644 (13) A

(43) Date of A Publication 06.02.2002

(21) Application No 0017515.8

(22) Date of Filing 15.07.2000

(71) Applicant(s)
Donald Munro Miller
12 Monawee, 316 Main Road, KENILWORTH 7708, South Africa

(72) Inventor(s)
Donald Munro Miller

(74) Agent and/or Address for Service
Elizabeth W Mathew
Eastfield House, 44 Beverley Road, Southcave, BROUGH, N Humberside, HU15 2AU, United Kingdom

(51) INT CL[7]
A61M 16/04

(52) UK CL (Edition T)
A5R RGEX

(56) Documents Cited
WO 98/16273 A

(58) Field of Search
UK CL (Edition S) **A5R RGEX**
INT CL[7] **A61M 16/04**
ONLINE: EPODOC, WPI, JAPIO

(54) Abstract Title
A streamlined liner of the pharygeal airway (SLIPA)

(57) An artificial airway device to facilitate ventilation of the lungs in unconscious patients, comprises a flexible tube made of a material which retains its shape when deformed and is open at both ends. The tube comprises a first tubular part (11) which may be attached to breathing apparatus and a second expanded saccular part (14) which communicates with the entrance to the larynx. The second part conforms to the shape of the hypopharynx for the purpose of lining and sealing it when it is placed posterior of the larynx at the base of the tongue. It also seals the outlets from the pharynx except via the two open ends (12,13). The airway is made in a variety of sizes so that an inflatable cuff is not needed.

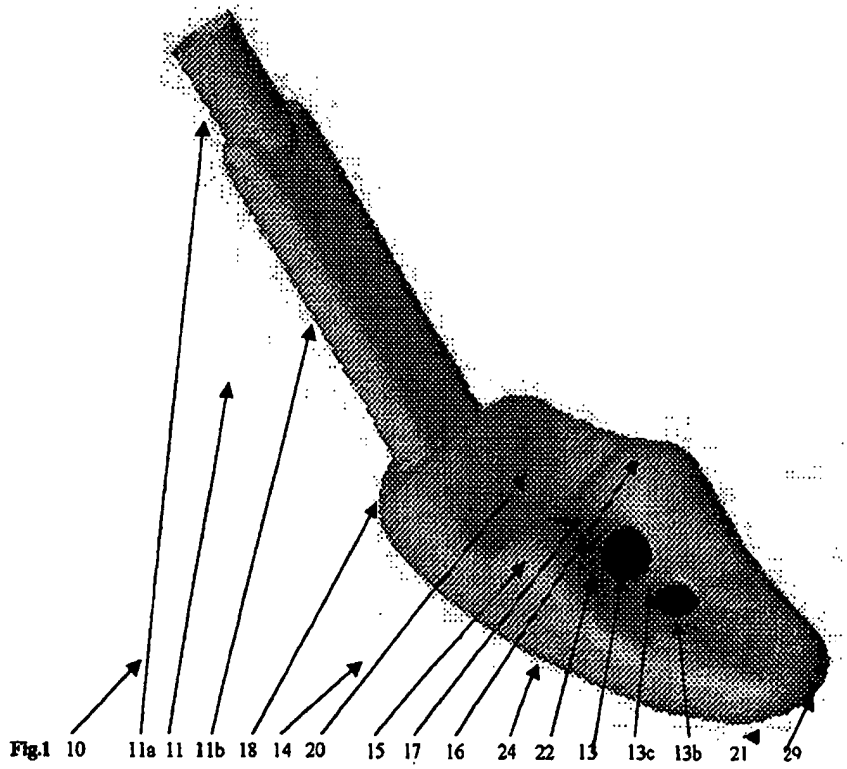


Fig.1

GB 2 364 644 A

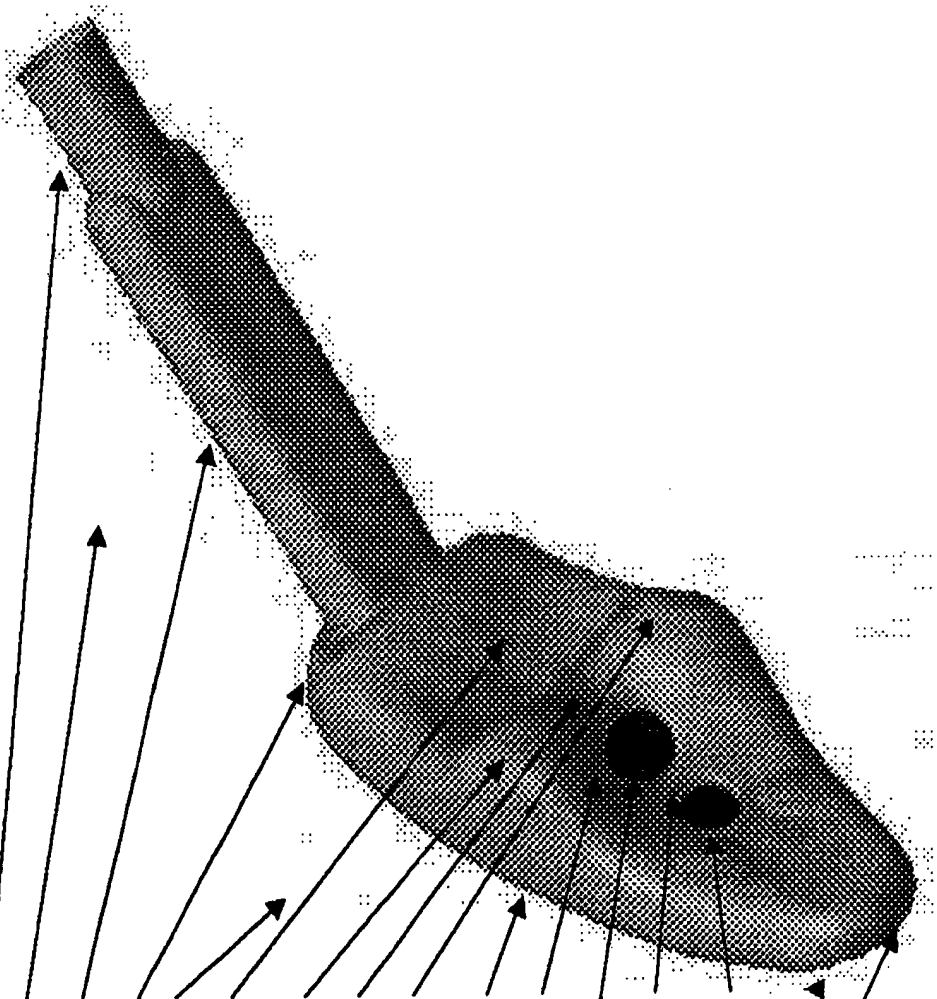

10
11a
11
11b
18
14
20
15
17
16
24
22
13
13c
13b
21
29

Fig.1

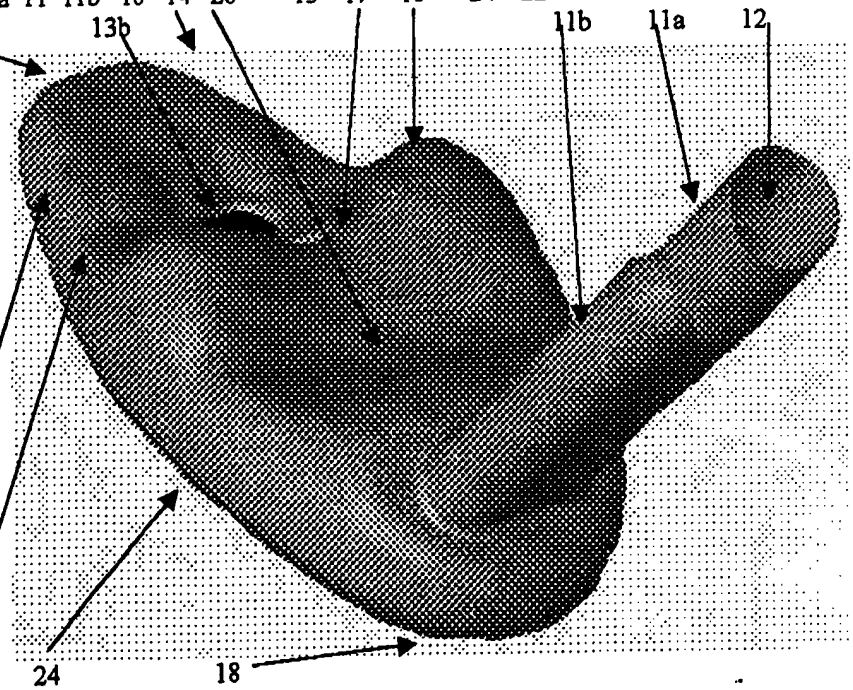

29
13b
11b
11a
12
21
22
24
18

Fig.2

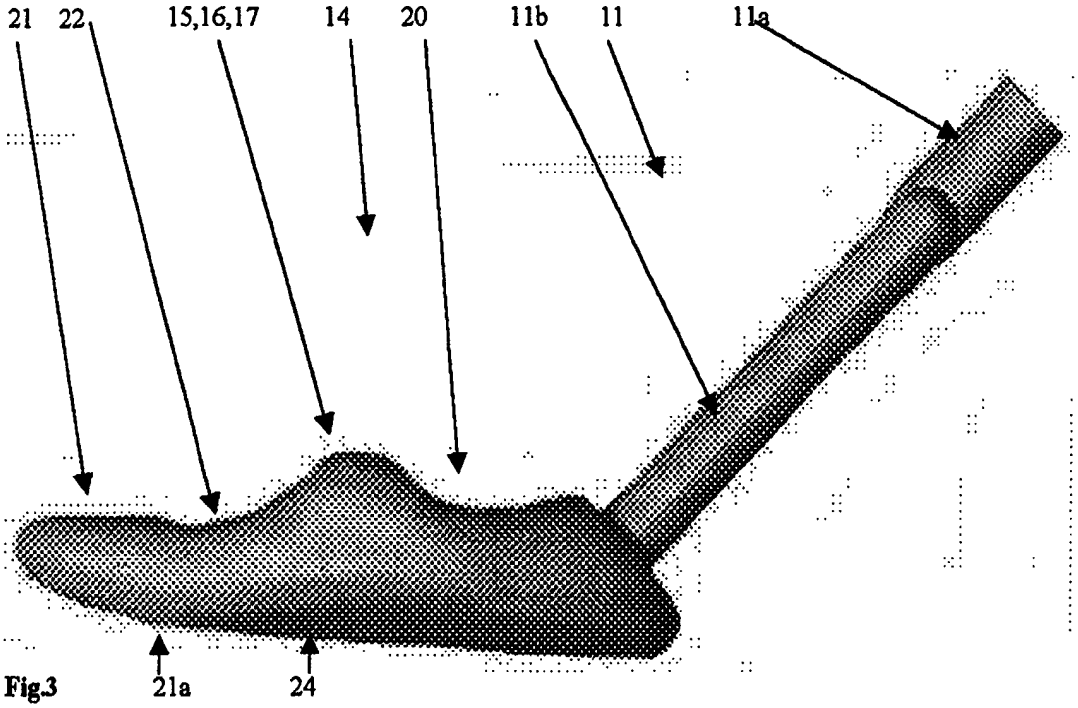
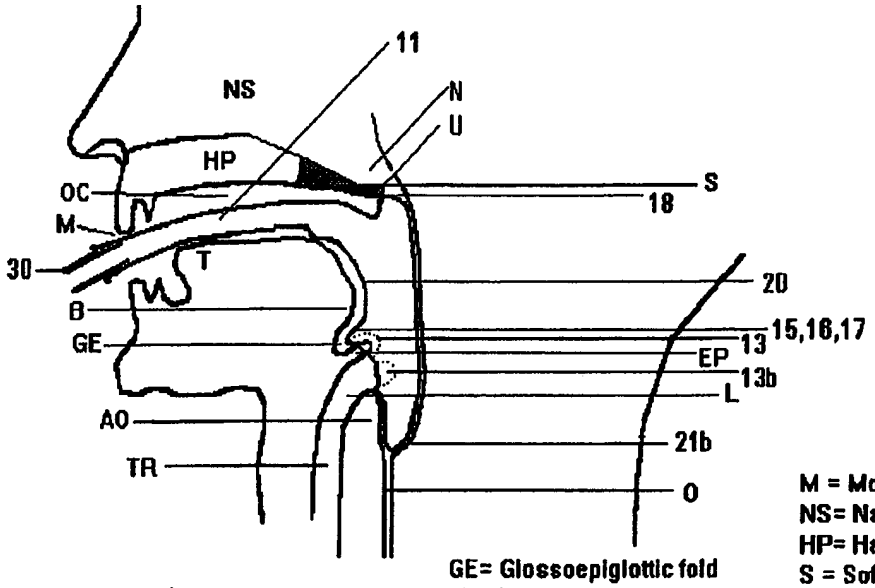


Fig.3



GE= Glossoepiglottic fold
TR= Trachea
AO= Anterior Oesophageal wall
L = Larynx
EP= Epiglottis
T = Tongue
N = Nasopharynx

M = Mouth
NS= Nasal cavity
HP= Hard palate
S = Soft palate
U = Uvula
OC= oral cavity
P = Pharynx
B = Base of the tongue
O = Oesophagus

Fig.4

Fig.5

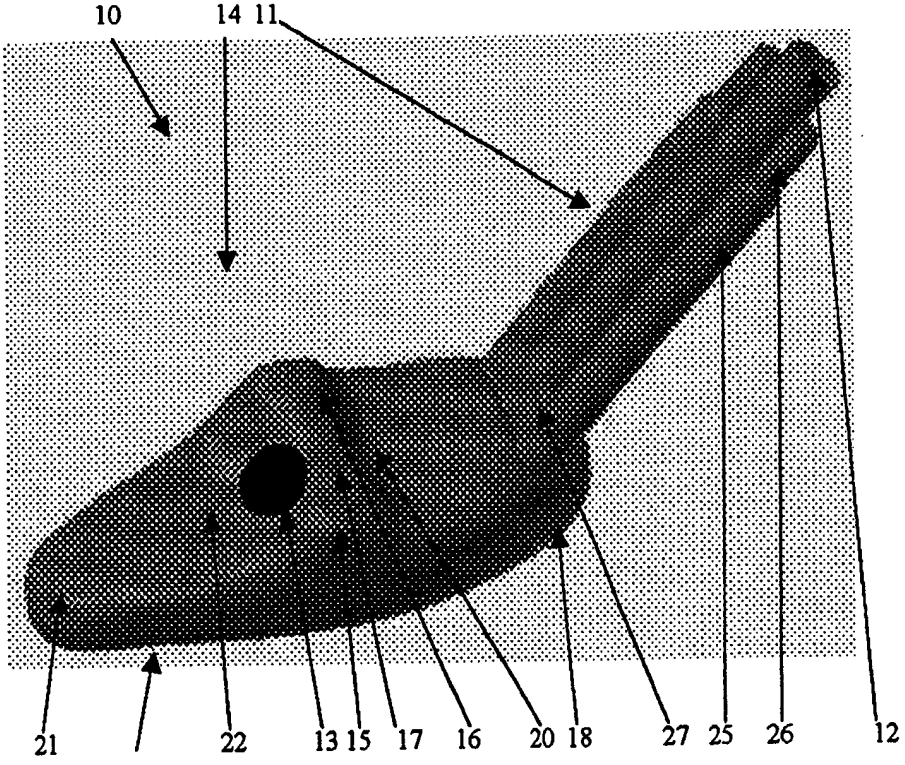


Fig.6

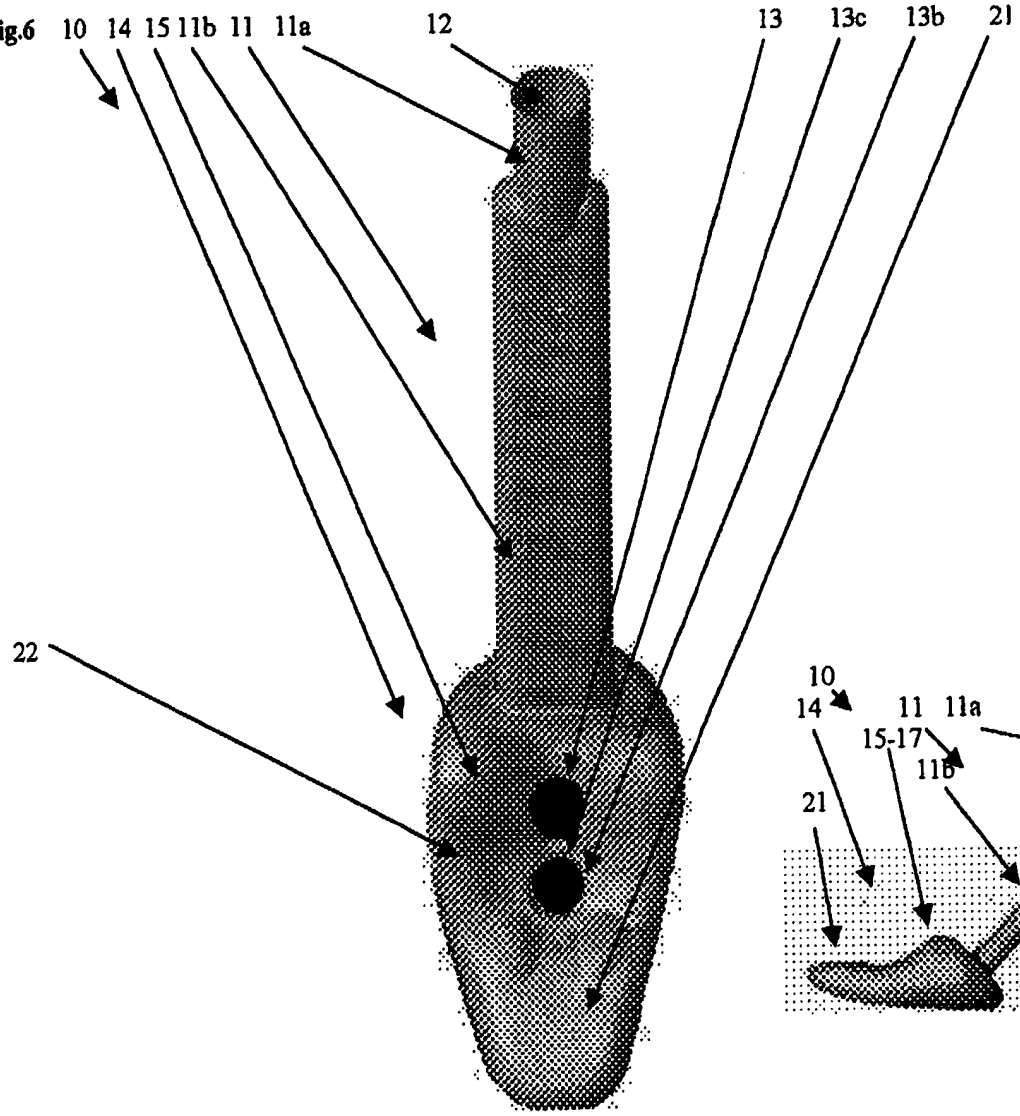


Fig.6b

Fig.7

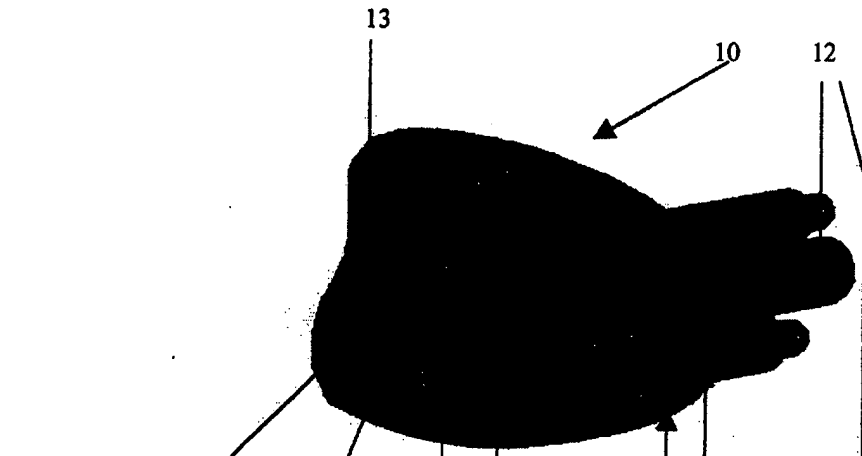


Fig.8

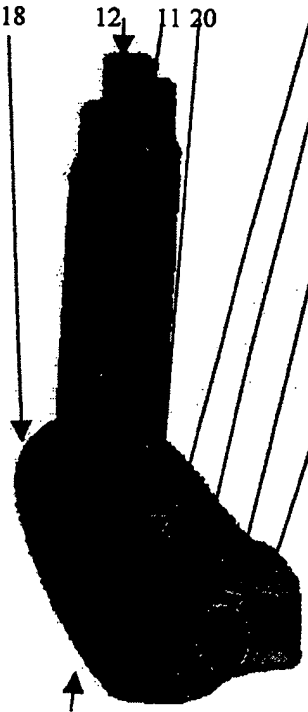
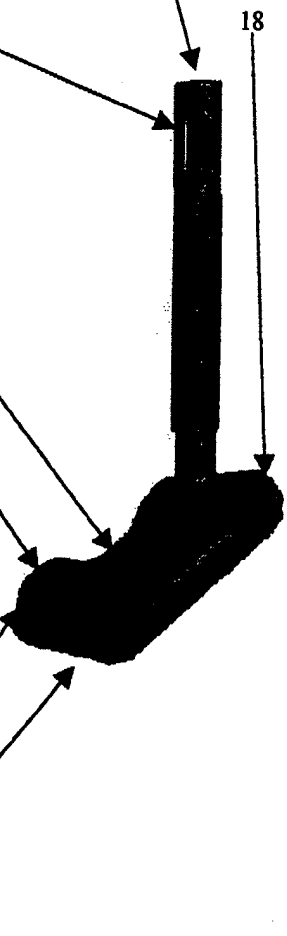


Fig.9



Title: A Streamlined Liner of the Pharyngeal Airway (SLIPA)

SCOPE OF THE INVENTION:

The present invention relates to respiratory apparatus in the form of an artificial airway device for placement into the oropharynx of an unconscious patient to maintain airway patency, to permit attachment to respiratory apparatus, to permit either spontaneous or controlled positive pressure ventilation and to prevent the inhalation into the lungs of extraneous matter such as vomitus or blood.

THE STATE OF THE ART: An unconscious patient may have need of some or all four of the above objectives for supporting respiration and, therefore, life. During anaesthesia or resuscitation this is achieved by means of an endotracheal tube with an inflatable cuff around the end which is placed within the trachea, or a laryngeal mask airway (LMA), which also involves the use of an inflatable cuff at the end of a tube, the end of which is placed around the entrance to the larynx and within the pharynx, or an oesophageal obstructor airway (EOA) named "Combitube" or derivative. This comprises a double lumen double cuffed tube, the longer tube with attached cuff passes into the oesophagus for the purpose of sealing and isolating contents which may enter the oesophagus from below or to prevent the escape of gas under pressure from above from entering the stomach. The shorter tube for ventilating the lungs ends within the pharynx, the oronasal outlet from the pharynx being sealed off within the pharynx by means of the second cuff which surrounds both tubes, which when inflated allows for positive pressure to develop within the pharynx. Sometimes, an oral or nasal airway tube for preventing obstruction of the airway is used in combination with a facemask. More recently a cuffed oropharyngeal airway (COPA) has been introduced by Mallinckrodt Medical, Inc, US patent No. 5,743,256, (May 30, 1995) which can be used to achieve 3 of the four objectives stated above but fails to protect the lungs from extraneous matter that enters the pharynx from entering the lungs. Numerous other double cuff inflating devices are appearing in the current market and may be classed as derivatives of the EOA and COPA above e.g. that of Sato et al US patent No. 5,743,258 (April 28, 1998).

The maximum inflation pressure that can be used before gas leakage occurs around the cuffs limits the application of controlled ventilation by the latter two methods. They also run the risk of inflating the stomach and do not provide a secure airway from the possible aspiration of vomitus. The LMA provides a partial seal of the oesophagus but regurgitation if it gets past the seal is more likely to pass into the inflatable bag cavity in the case of the LMA from whence the contents are easily funneled into the larynx. The COPA does not provide any seal of the oesophagus. The Combitube would appear to be an effective device, for controlled ventilation, sealing off the oesophagus, but its correct placement can pose problems, either too deep or not deep enough. It is also rather elaborate and expensive. The LMA would appear to be ideal except for the fact that the pressures that can be generated in controlled ventilation are limited as the mask could be dislodged at higher inflation pressures. In addition, although it is partially effective in isolating the airway from extraneous matter in the pharynx, should any extraneous matter enter the lumen of the mask, which does not provide a high quality isolation of the trachea from pharyngeal matter, it will tend to be funneled into the larynx. To overcome this disadvantage an improved LMA named the 'Proseal' LMA incorporates a moderate bore tube for removing liquid that may accumulate in the mask region of the airway by suction or siphonage and is disclosed in Japanese Patent No. 2-283378 (Nov. 20.1990). The placement in the trachea of the endotracheal tube is the most effective means of achieving all four of the above objectives, however, its use requires experience, skill and the use of a laryngoscope which in turn has its own unwanted side effects consequent upon powerful neural reflex actions. Its placement may also require the use of muscle relaxing drugs.

It is the objective of the present invention to provide an appropriately shaped artificial airway which will obviate the need for a cuff-blowing up mechanism for sealing purposes and yet one that retains most of the advantages of the use of endotracheal tubes, Combitubes or laryngeal masks in the above mentioned circumstances and to avoid, as far as it is possible, their individual disadvantages.

DESCRIPTION:

An artificial airway device, that is a combined obturator and airway device without penetration into the interior of the larynx, nevertheless, for use in place of an endotracheal tube or equivalent, to facilitate ventilation of the lung in unconscious patients, is in the form of a pharyngeal liner airway comprising a preformed flexible tube, made of flexible material of a consistency that is characterised by the retention of its shape when temporarily deformed, open at both ends, which may be divided into a first tubular part with first end and a second expanded saccular part with second end, the first end of the first tubular part, which is for the purpose of attaching to breathing apparatus and conducting gases to and from the said second expanded part that comprises a preformed hollow saccular dilatation that conforms to the shape and size of the hypopharynx for the purpose of lining and sealing therein when it is placed posterior of the larynx at the base of the tongue and for the purpose of sealing outlets or outlet from the pharynx except via the said two ends of the said device, the said second end placed in the said saccular dilatation proximal to the said sealing areas of the said second saccular part and for the purpose of unencumbered open communication with the entrance to the larynx.

This is a type of pharyngeal outlet obturator airway (POOBAIR) and may include the standard 15 mm tapered attachment connector inserted into said first end for attachment to breathing apparatus, said first part extending from the first end through the mouth, where it may bend to conform to the gentle curved shape of the tongue pushing against the hard palate, to the said second expanded part that is located in the pharynx, where the said saccular dilation part of the tube takes a right angled bend as it hooks into the base of the tongue and expands into a preformed saccular dilatation that forms an upward-outlet-from-the-pharynx gas tight seal (the said obturator function) in the space that extends from the base of the tongue or glossoepiglottic fold and the two lateral paraglottic crypts or valleculae in the anterior aspect, and in a crescent shaped arc seals at the same level against the lateral and posterior pharyngeal walls with a proximal-to-the-seal opening in the base of the said saccular dilatation that corresponds with the laryngeal opening, the said second end, for the passage of gas to flow between the larynx and the airway device. The said saccular expanded second part may, in addition, extend further and with benefit include each or all of:

a) a saccular rounded wedge-shaped extension of the said saccular expanded second part that is for the purpose of protruding into the entrance of the oesophagus to seal the "downward" outlet from the pharynx into the oesophagus thereby closing off all outlets, obturating downward and upward outlets from the pharynx except via the said two open ends of the device, the said second end opening anteriorly to correspond with the laryngeal opening.
b) With the upward outlet obturator already described forming the base of a heart-shaped expanded saccular second part, an extension of the same in a downward direction into the oesophagus comprising the apex of the said heart-shaped second part that is for the purpose of protruding into the entrance of the oesophagus to seal the "downward" outlet from the pharynx into the oesophagus and sealing around the entrance to the larynx thereby providing a means of collecting secretions within the hollow heart-shaped saccular sealing means, closing off all outlets from the pharynx, obturating downward and upward outlets from the pharynx except via the said two open ends of the device, the said second end opening anteriorly to correspond with the laryngeal opening.
c) an upward extension to incorporate a heel-shape that corresponds to the nasopharynx and soft palate for the purpose of ensuring a more stable location of the sealing airway in the pharynx by anchoring the said device in its position in the hypopharynx as it settles into the nasopharynx and soft palate in such a way as to prevent expulsion as the airway pressure rises.
d) a preformed heart-shaped saccular dilatation that forms an upward-outlet-from-the-pharynx gas tight seal in the space that extends from the base of the tongue or glossoepiglottic fold and the two lateral paraglottic crypts or valleculae in the anterior aspect, the lateral and posterior pharyngeal walls and extending to the apex of the triangular heart shape that corresponds to the nasopharynx and soft palate.

An artificial airway device, without penetration into the interior of the larynx, nevertheless, for use in place of an endotracheal tube or equivalent, to facilitate ventilation of the lung in unconscious patients, is in the form of a pharyngeal liner airway comprising a preformed flexible tube open at both ends, which may be divided into a first tubular part with first end and a second expanded saccular part with second end, the first end of the first tubular part comprising a tube with standard attachment connector for attachment to breathing apparatus that extends from the first end through the mouth to the expanded part that is located in the pharynx, where the tube expands into a preformed slipper-shaped saccular dilatation that conforms to the shape of the pharynx sealing off all the outlets from the pharynx except via the two said open ends of the device, the said slipper-shaped saccular dilatation forming an upward-outlet-from-the-pharynx gas tight seal in the space that extends from the base of the tongue or glossoepiglottic fold and the two paraglossal crypts or valleculae in the anterior aspect, the lateral and posterior pharyngeal walls and extending to the 'heel' of the shoe-shaped dilatation that corresponds to the nasopharynx and soft palate with a wedge-shaped 'toe-

end' of the slipper-shaped dilatation protruding into the entrance of the oesophagus to seal the "downward" outlet from the pharynx into the oesophagus with the second end opening anteriorly towards the laryngeal opening a short distance below the widest in cross-sectional plane part of the saccular dilatation where sealing occurs at the level of the base of the tongue.

An artificial airway device, without penetration into the interior of the larynx, nevertheless, for use in place of an endotracheal tube or equivalent, to facilitate ventilation of the lung in unconscious patients, is in the form of a pharyngeal liner airway comprising a preformed flexible tube open at both ends, which may be divided into a first tubular part with first end and a second expanded saccular part with second end, the first end of the first tubular part comprising a tube with standard attachment connector for attachment to breathing apparatus that extends from the first end through the mouth to the expanded part that is located in the pharynx, where the tube expands into a preformed hollow heart-shaped saccular dilatation, thus lining and conforming to the shape of the hypopharynx, posterior of the larynx from the base of the tongue to the entrance of the oesphagus, with second end opening in the anterior aspect thus corresponding with the laryngeal opening, said hollow heart-shaped saccular sealing means providing a means of collecting secretions within the said device.

The one common characteristic in all the above possible artificial airway devices is that the need for an inflatable cuff to expand into the right size pharyngeal cavity is obviated because it is made in a variety of sizes so that the appropriate size to be chosen may specifically match the size of each prospective patient's pharyngeal cavity.

DESCRIPTION RELATING THE INVENTION MORE SPECIFICALLY TO THE ENCLOSED NUMBERED DRAWINGS:

A three dimensional drawing of the invention is shown from an oblique anterior view in Fig. 1, vertical oblique anterior view in Fig. 2 and a lateral view in Fig. 3 and a 2 dimensional lateral longitudinal-section of the device in relation to the anatomy in Fig. 4. Figure 5 is a very small variation of the same using the same numbering system. An artificial airway device 10, without penetration into the interior of the larynx, nevertheless, for use in place of an endotracheal tube or equivalent, to facilitate ventilation of the lung in unconscious patients, is in the form of a pharyngeal liner airway (PLA) 10. It comprises a preformed flexible tube divided into two parts 11 and 14, which is open at both ends, first end 12 and second end 13 and 13b. The first end comprises a tube with standard attachment connector inserted into the end 12 (not shown except connector 30 in Fig.4) for attachment to breathing apparatus. The said PLA extends from the first end 12 through the mouth via the tube 11, 11a the entrance part and 11b that is oval in cross-section and extending to the second expanded part 14 that would normally occupy a position in the pharynx. The second part comprises a preformed shoe-shaped saccular dilatation 14 that conforms to the shape of the pharynx sealing off all the outlets from the pharynx except via the two said open ends 12 and 13 of the device 10. The said shoe-shaped saccular dilatation 14 having anterior and posterior aspects, forming an upward-outlet-from-the-pharynx gas tight seal at the anterior aspect sites 15,16,17 and posterior site 24 in the space that extends from the base of the tongue (B in Fig.4) or glossoepiglottic fold GE and the two lateral paraglottic crypts or valleculae to the lateral and posterior pharyngeal wall and extending superiorly to the 'heel' 18 of the shoe-shaped dilatation that corresponds to the nasopharynx N and soft palate S. The anterior saccular dilatation that seals between the base of the tongue and the epiglottis 15,16,17 is rounded 'V' shaped in longitudinal section in its axial plane thereby avoiding backward displacement of the epiglottis with resultant partial inspiratory obstruction. The 'downward' outlet from the pharynx is sealed by means of a wedge-shaped 'toe-end' 21 of the 'shoe-shaped dilatation protruding into the entrance of the oesophagus O. The second end 13 opens in an anterior direction towards and opposite the laryngeal opening L a short distance below the widest in cross-sectional plane part of the saccular dilatation that corresponds to the 2 paraglottic crypt protrusions 15,16 and the interconnecting dip 17, where sealing occurs at the level of the base of the tongue B, all on the said anterior aspect of the saccular dilatation 14.

Alternatively, in Fig. 6, with sideview Fig.6b, an artificial airway device 10, for use in place of an endotracheal tube to facilitate ventilation of the lung in unconscious patients, is in the form of a pharyngeal outlet obturator airway 10 or POOBAIR, comprising a flexible tube 11 that extends from the first end 12 through the mouth via the tube 11 to the pharynx, and the location of the second end with flexible preformed hollow heart-shaped saccular dilatation 14 , thus lining and conforming to the shape of the hypopharynx, posterior of the larynx from the base of the tongue to the entrance of the oesphagus, with second end opening 13 and 13b in the anterior aspect thus corresponding with the

laryngeal opening, said hollow heart-shaped saccular sealing means with wedged apex or toe 21 for protruding into the entrance of the oesophagus and providing a means of collecting secretions within the said device.

Alternatively, in Figs 7,8 and 9 an artificial airway device 10, for use in place of an endotracheal tube to facilitate ventilation of the lung in unconscious patients, is in the form of a pharyngeal outlet obturator airway 10 or POOBAIR, comprising a flexible tube 11 that extends from the first end 12 through the mouth via the tube 11 to the pharynx, and the location of the second end with flexible saccular dilated portion 14 corresponding to the shape of the heart-shaped upward outlet of the pharynx. The said heart-shaped saccular dilatation 14 forming an upward-outlet-from-the-pharynx gas tight seal at the sites 15,16,17 and 18 in the space that extends from the base of the tongue (B in Fig.4) or glossoepiglottic fold GE and the two lateral paraglottic crypts or valleculae in the anterior aspect that correspond with protrusions 15 and 17, the lateral and posterior pharyngeal walls 24 and extending to the apex 18 of the heart-shaped dilatation that corresponds to the nasopharynx N and soft palate S.

In its preferred form there may be an additional wedge-shaped protrusion 21 (in Figs 1-4) to seal the "downward" outlet from the pharynx into the oesophagus (O in Figure 4), an anterior protrusion 15,16,17 shaped to occupy and fill the space (comprising two valleculae [corresponding with protrusions 15 and 17] and the glossoepiglottic fold GE corresponding with 17) between the epiglottis E and the base of the tongue B, an "upward" protrusion 18 into the nasopharynx N and soft palate S, which together with the anterior vallecular protrusion 15-17, lateral and posterior pharyngeal aspect 24 seals the "upward" outlets and prevents gas under pressure within the pharyngeal cavity from escaping via the oral and nasal air passages. At least one opening 13 in the said saccular pharyngeal shaped sac 14 at the level of the entrance to the larynx L and trachea T and in the concave surface 22 between the said anterior vallecular protrusion 15-17 and downward oesophageal protrusion 21 for the purpose of ventilating the lungs.

It may be appreciated that, when in position, the concavity 20 lies over the posterior portion of the tongue with the protrusion 15-17 hooked around the base of the tongue and the 'shoe-shaped saccular dilation fitting precisely into the shape of the pharynx and with almost a right angled bend. Airway pressure that may rise during positive pressure ventilation would tend to push the device in the direction of the nasopharyngeal cavity N and will be held in position by the nasopharyngeal protrusion 18, preventing it from being dislodged. When it is desirable to remove the device, this may be achieved by pulling on the tube 11, which automatically dislodges 18 in an appropriate direction from the soft palate S and nasopharyngeal cavity N.

It may also be appreciated that should secretions or stomach contents accumulate in the pharynx for any reason, the oesophageal protrusion 21and indeed most of the capacity of the saccular portion 14 of the hollow device 10 provides a 'sump' for the collection of fluid that can be sucked out by means of a suction catheter that may be passed via the end 12 and tubular portion 11 at a convenient time. In Figs 1.2.3 the toe 21 is angulated towards the larynx at the level of 21a which has the beneficial effect of ducting possible regurgitation fluids in the posterior and gravity dependent direction. The outlets 13 and 13b may be matched by outlets diametrically opposite on the posterior surface 24 (not shown in the drawings), which may provide a means for collecting secretions within the 'sump-performing' device.

For quick easy 'blind'(i.e. without the need for a laryngoscope) insertion of the PLA, the blind wedge-shaped 'toe' for the purpose of placement in the entrance of the oesophagus, 21in Fig.3, is shaped with an anterior curve (see 21b in longitudinal section in Fig.4) or/and an angulation towards the laryngeal opening at the level 21a in Fig.3 with the appearance of an upturned toe so as to facilitate the negotiation of the PLA 10 around the right angled bend of the pharyngeal cavity at the level of the base of the tongue and nasopharynx. It also serves the purpose of better conformation to the shape of the pharyngeal cavity.

For quick easy 'blind'(i.e. without the need for a laryngoscope) insertion of the PLA, it may be necessary to use an introducer (a stiff flexible curved rod) with its tip inserted into the PLA 10 from the said first end as far as the tip of the oesophageal protrusion 21, so that possible folding of the device is avoided.

In Fig. 5, in addition to the one tube 11 leading into the saccular dilated part 14 of 10, there may be one or two additional tubes 25 running parallel to 11 which may serve the purpose of providing a measure of rigidity to the tube portion 11 and also by providing an alternative means of applying suction, for gas sampling or use of an endoscope or the placement of a nasogastric tube. The narrower section 26 may be a diameter that is suited to the passing of a nasogastric tube in a self-sealing manner, with the rounded end cut off. The wider diameter 25 may be suited to

passing other instruments such as an endoscope or a thick walled closed plastic tube or solid rod for serving as a bite protection means.
Suction and even endoscopy may be performed either via one of the two tubes 25 that run parallel to tube 11, without the need to stop providing the supply of anaesthetic gases.
At the site 29, a small protrusion to match the diameter of the protrusion 26 and the end of tube 25 may be provided for passing a nasogastric tube should such a tube be indicated during surgery. Under these circumstances, both ends would have to be cut off in order to pass as suitable size nasogastric tube that will be self-sealing in the relevant sites 26 and 29.

In its preferred form, the device is manufactured by means of blow-moulding a grade of soft thermoplastic with rubbery characteristics and is blow moulded into the shape described above and illustrated by the diagrams in Figures 1,2,3 and 4. The said pharyngeal liner airway is ideally suited to manufacture by means of blow-moulding with the use of suitable flexible materials for retaining their shape and without causing excessive pressure against the pharyngeal walls when in position. It is desirable that the tubes 11 and 25 enter the saccular portion 14 at an appropriate angle to conform to the shape of the pharynx and outlet via the mouth. In order that this be achieved, a measure of flexibility is required and achieved at the junction of the parallel tubes 11 and 25 with the saccular portion 14 by means of a narrowing in the axial plane and coalescing the three tubes 11 and 25 into one oval in cross-section portion 27. In addition, the entrance of the narrowed portion 27 is perpendicular to the walls of the saccular dilated part 14 for the same purpose of flexibility. It may be preferred to do away with most of the length of the parallel tubes 11 and 25 and extend the oval cross-section portion 27 throughout most of the passage in the mouth to achieve flexibility in the first part of the tube 11b in Figs.1,2 and 3 that occupies a position in the mouth.

The said anterior port 13 may, with advantage, comprise two ports 13 and 13 b axially arranged as shown in Figs 1 and 2, so that should an epiglottis E which tends to protrude into the concavity 22 and even into the upper port 13 with the possibility of partially obstructing the same, may be prevented from obstructing the lower port 13b by means of the horizontal bar 13c dividing the two ports 13 and 13b thereby preventing in drawing of the epiglottis against the laryngeal opening L.

As the device 10 is hollow, there is capacity for placement of porous hydrophobic material or other filter elements within the second saccular expanded part 14 to provide heat and moisture exchange within the device and filtration.

CLAIMS:

1. An artificial airway device, that is a combined obturator and airway device without penetration into the interior of the larynx, nevertheless, for use in place of an endotracheal tube or equivalent, to facilitate ventilation of the lung in unconscious patients, is in the form of a pharyngeal liner airway comprising a preformed flexible tube, made of flexible material of a consistency that is characterised by the retention of its shape when temporarily deformed, open at both ends, which may be divided into a first tubular part with first end and a second expanded saccular part with second end, the first end of the first tubular part, which is for the purpose of attaching to breathing apparatus and conducting gases to and from the said second expanded part that comprises a preformed hollow saccular dilatation that conforms to the shape and size of the hypopharynx for the purpose of lining and sealing therein when it is placed posterior of the larynx at the base of the tongue and for the purpose of sealing outlets or outlet from the pharynx except via the said two ends of the said device, the said second end placed in the said saccular dilatation proximal to the said sealing areas of the said second saccular part and for the purpose of unencumbered open communication with the entrance to the larynx.
2. An artificial airway device according to claim 1, where the said saccular dilation part of the tube takes a right angled bend for the purpose of hooking into the base of the tongue and expands into a preformed saccular dilatation that forms an upward-outlet-from-the-pharynx gas tight seal (the said obturator function) in the space that extends from the base of the tongue or glossoepiglottic fold and the two lateral paraglottic crypts or valleculae in the anterior aspect, and in a crescent shaped arc seals at the same level against the lateral and posterior pharyngeal walls with downward and anterior opening in the base of the said saccular dilatation that corresponds with the laryngeal opening, the said second end, for the passage of gas to flow between the larynx and the airway device.
3. An artificial airway device according to claim 1 or 2 wherein the said saccular expanded second part may include the upward outlet obturator already described forming the base of a heart-shaped expanded saccular second part, an extension of the same in a downward direction for the purpose of projecting into the oesophagus comprising the apex of the said heart-shaped second part that is for the purpose of protruding into the entrance of the oesophagus to seal the "downward" outlet from the pharynx into the oesophagus and sealing around the entrance to the larynx thereby providing a means of collecting secretions within the hollow heart-shaped saccular sealing means, closing off all outlets from the pharynx, obturating downward and upward outlets from the pharynx except via the said two open ends of the device, the said second end opening anteriorly to correspond with the laryngeal opening.
4. An artificial airway device according to claims 1 and 2 wherein the said saccular expanded second part may comprise a preformed heart-shaped saccular dilatation that forms an upward-outlet-from-the-pharynx gas tight seal in the space that extends from the base of the tongue or glossoepiglottic fold and the two lateral paraglottic crypts or valleculae in the anterior aspect, the lateral and posterior pharyngeal walls and extending to the apex of the triangular heart shape that corresponds to the nasopharynx and soft palate thereby anchoring the device between the base of the tongue and the soft palate.
5. An artificial airway device according to any of the preceding claims wherein the said saccular expanded second part may include a saccular rounded wedge-shaped extension that is for the purpose of protruding into the entrance of the oesophagus to seal the "downward" outlet from the pharynx into the oesophagus thereby closing off all outlets, obturating downward and upward outlets from the pharynx except via the said two open ends of the device, the said second end opening anteriorly to correspond with the laryngeal opening.
6. An artificial airway device according to claims 1,2, and 5 where the said second expanded part comprises a preformed shoe-shaped saccular dilatation that conforms to the shape of the pharynx for the purpose of sealing off all the outlets from the pharynx except via the two said open ends of the device, the said shoe-shaped saccular dilatation for the purpose of forming an upward-outlet-from-the-pharynx gas tight seal in the space that extends from the base of the tongue or glossoepiglottic fold and the two lateral paraglottic crypts or valleculae in the anterior aspect, the lateral and posterior pharyngeal walls and extending to the 'heel' of the shoe-shaped dilatation that corresponds to the nasopharynx and soft palate with a wedge-shaped 'toe-end' of the 'shoe-shaped dilatation protruding into the entrance of the oesophagus to seal the "downward" outlet from the pharynx into the oesophagus with the second end opening anteriorly towards the laryngeal opening a short distance below the widest in cross-sectional plane part of the saccular dilatation which is for the purpose of sealing at the level of the base of the tongue.
7. An artificial airway device according to claims 1,3,5 and 6 wherein the said wedge-shaped oesophageal portion of the saccular dilatation may act as a blind sump for the purpose of collecting and later removal by suction of any liquid that may accumulate in the pharynx thereby preventing secretions from entering the larynx, trachea and lungs.

8. An artificial airway device according to any of the preceding claims wherein the said saccular dilatation is a preformed shape and made of soft flexible material that tends to maintain its shape when distorted effecting a seal that does not require an inflatable balloon.
9. An artificial airway device according to any of the preceding claims wherein the part of the said saccular dilatation that is for the purpose of sealing between the base of the tongue and the epiglottis is rounded 'V' shaped in longitudinal section in its axial plane thereby avoiding backward displacement of the epiglottis with resultant partial inspiratory obstruction.
10. An artificial airway device according to any of the preceding claims wherein the part of the said flexible saccular dilatation that is for the purpose of sealing the 'upward' outlet from the pharynx by means of maintenance of the gentle lateral force against the pharyngeal walls by means of the balance of intralumen and extralumen pressure when higher inflation pressures are used.
11. An artificial airway device according to any of the claims 1,3, 5 to 10 wherein quick easy 'blind'(i.e. without the need for a laryngoscope) insertion of the device may be made easier by a wedge-shaped oesophageal pouch or 'upturned toe' section of the shoe shape with an anterior curve or an angulation towards the laryngeal opening so as to facilitate the negotiation of the device around the right angled bend of the pharyngeal cavity at the level of the base of the tongue and nasopharynx.
12. An artificial airway device according to any of the claims 1,3, 5 to 11 wherein quick easy 'blind'(i.e. without the need for a laryngoscope) insertion of the device, can be achieved by means of an introducer (a stiff flexible curved rod) with its tip inserted into the device throughout its length and into a blind wedge-shaped pouch representing the part for entrance into the oesophagus.
13. An artificial airway device according to any of the claims 1,3, 5 to 12 wherein the said wedge-shaped oesophageal portion of the saccular dilatation may include a small bore extension at the tip of the 'toe' shape for the purpose of passing a nasogastric tube, should the need arise.
14. An artificial airway device according to any of the claims 1,3, 5 to 13 where the said second anterior port in the concavity between the upward and downward sealing saccular dilatations may, with advantage, comprise two ports axially arranged with one above the other, so that should an epiglottis which may tend to protrude into the upper concavity and even into the upper port with the possibility of partially obstructing the same, may be prevented from obstructing the lower port by means of the horizontal bar dividing the two ports thereby preventing in drawing of the epiglottis into the laryngeal opening.
15. An artificial airway device according to any of the preceding claims which may include a second or third tube extending from the saccular dilatation portion of the airway device in parallel with the first tube for the purpose of passing a nasogastric tube and/or a fibreoptic instrument.
16. An artificial airway device according to any of the preceding claims which may include a second or third tube extending from the saccular dilatation portion of the airway device in parallel with the first tube for the purpose of placing a bite-resistant tube to ensure patency of the main central airway tube.
17. An artificial airway device according to any of the preceding claims where flexibility is achieved at the junction of the first tube part with the said second saccular part of hollow airway device by means of a narrowing in the axial plane and oval shaping in cross-section and perpendicular entrance to the walls of the saccular dilated part for the same purpose of flexibility.
18. An artificial airway device according to any of the preceding claims where flexibility of the first part of the tube that occupies a position in the mouth is achieved by means of an oval cross-section throughout most of its passage through the mouth.
19. An artificial airway device according to any of the preceding claims wherein the said pharyngeal liner airway is manufactured as a blow moulded device of suitable flexible materials for retaining its shape and without causing excessive pressure against the pharyngeal walls when in position.
20. An artificial airway device according to any of the preceding claims wherein the said pharyngeal liner airway contains porous hydrophobic material or other filter elements within the second expanded saccular part to provide heat and moisture exchange within the device and filtration.
21. An artificial airway device according to any of the preceding claims which does not need an inflatable cuff to expand into the right size pharyngeal cavity because said device is made in a variety of sizes so that the appropriate size to be chosen may specifically match the size of each prospective patient's pharyngeal cavity.
22. An artificial airway device substantially as hereinbefore described and as illustrated in the accompanying drawings.

Application No:	GB 0017515.8	**Examiner:**	Susan Chalmers (Mrs)
Claims searched:	1-22	**Date of search:**	8 January 2001

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R: RGEX

Int Cl (Ed.7): A61M: 16/04

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
A	WO 98/16273 A (AUGUSTINE MEDICAL) see eg Figures 14-21	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.